

REMARKS

Upon entry of the claim amendments, claims 1-4, 8-10 and 23 are all the claims pending in the application. Claims 5-7, 11-22 and 24-28 have been canceled. Claims 1 and 4 have been amended. Support for the claim amendments can be found throughout the specification and in the originally filed claims.

Claims 1 and 4 have been amended to recite specific cancers, ovarian, pancreatic and/or prostate cancers, treated with a combination of the compound of formula 12 and each specific chemotherapeutic agent, carboplatin, paclitaxel, gemcitabine or doxorubicin.

Claim 4 has been further amended to delete the recitation of “prophylaxis.”

Accordingly, no new matter has been introduced by these amendments to the claims.

I. Withdrawn Rejections

Applicant thanks the Examiner for withdrawing the previous written description rejections of claims 1-4, 6-10, 23 and 26-28 and the previous enablement rejections of claims 1-3, 6-7, 13 and 26-28 under 35 U.S.C. § 112, first paragraph.

II. Allowable Subject Matter

Claim 2 stands objected to as being dependent upon a rejected base claim.

For the reasons set forth below, Applicant respectfully submits that the base claim, claim 1 is allowable and thus request withdrawal of the objection of claim 2.

III. Present Claims Comply With 35 U.S.C. § 112, Enablement Requirement

Claims 4 and 8-10 stand rejected under 35 U.S.C. § 112, first paragraph, for the alleged lack of enablement.

The Examiner states that claim 4 recites “prophylaxis” of cancer, which is not supported by the specification given unpredictability in treating cancer. Claims 8-10 depend from claim 4 and require the same limitations as claim 4.

Without agreeing with the Examiner, solely to expedite the prosecution, Applicant has amended claim 4 to delete the recitation of “prophylaxis.”

Accordingly, Applicant submits that the current amendment to the claim renders moot the above enablement rejection.

IV. Present Claims Are Patentable Over Kelly and Ekwurlbe

Claims 1, 3-4, 6-10, 13, 23 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kelly et al (WO 98/1008503) in view of Ekwurlbe et al (U.S. 6,380,405). Specifically, in response to Applicant’s previous claim amendments, the Examiner asserts that Applicant’s amendments do not limit the claims to the showing of synergy demonstrated by the specification.

Without agreeing with the Examiner, Applicant has amended independent claims 1 and 4 to recite i) that the cancer is ovarian, pancreatic or prostate cancer and the chemotherapeutic agent is cisplatin, ii) that the cancer is ovarian cancer and the chemotherapeutic agent is carboplatin, iii) that the cancer is ovarian or prostate cancer and the chemotherapeutic agent is paclitaxel, or iv) that the cancer is ovarian or pancreatic cancer and the chemotherapeutic agent is gemcitabine or doxorubicin. Claims 3, 6-10 and 13 depend from independent claim 1 or 4.

Specifically, in Example 1 of the present specification, Applicant has used presently claimed dehydroequol to increase the sensitivity of ovarian, prostate and pancreatic cancer cell lines to cisplatin. Moreover, in Example 2 of the present specification, Applicant has used

presently claimed dehydroequol to increase the sensitivity of ovarian cancer cell lines to cisplatin, carboplatin and paclitaxel.

Further, although the Examples in the specification employ only cisplatin, carboplatin, and paclitaxel, from reading the rest of the specification, one of ordinary skill in the art would also consider the rest of chemotherapeutic agents recited in the claims, gemcitabine and doxorubicin, as chemotherapeutic agents to which the recited compound can increase the sensitivity of cancer cells. *See* Page 3, lines 11-12 and pages 24-25. Moreover, Table 1 in Brown *et al.* (Idonoxil, *Drugs of the Future*, 2008, 33(10))¹ shows the increased sensitivities of i) ovarian and pancreatic cancer cells to cisplatin, ii) ovarian and prostate cancer cells to paclitaxel, and iii) ovarian and pancreatic cancer cells to gemcitabine and doxorubicin by administration of dehydroequol (also known as phenoxodiol or idonoxil) as recited in the present claims.

For the same reasons set forth above, Applicant respectfully submit that claim 23, reciting a pharmaceutical composition comprising a compound of formula 12 and a chemotherapeutic agent, cisplatin, carboplatin, paclitaxel, gemcitabine or doxorubicin, is allowable due to the synergetic effect of the claimed compound and the recited chemotherapeutic agents.

Accordingly, Applicant asserts that unexpected results showing a synergetic effect of the claimed compound and chemotherapeutic agents are commensurate in scope with the

¹ Previously submitted to the Office on October 9, 2009.

amended claims. Applicant respectfully requests that this enablement rejection be reconsidered and withdrawn.

V. Double Patenting Rejections

1. Claims 1, 3-4, 6-13 and 23-28 stand rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claim 1-21 of U.S. Patent No. 6,649,648 in view of Ekwurlbe *et al* (U.S. 6,380,405).

Without agreeing with the Examiner, Applicant has amended independent claims 1 and 4 to recite i) that the cancer is ovarian, pancreatic or prostate cancer and the chemotherapeutic agent is cisplatin, ii) that the cancer is ovarian cancer and the chemotherapeutic agent is carboplatin, iii) that the cancer is ovarian or prostate cancer and the chemotherapeutic agent is paclitaxel, or iv) that the cancer is ovarian or pancreatic cancer and the chemotherapeutic agent is gemcitabine or doxorubicin. Claims 3, 6-10 and 13 depend from independent claim 1 or 4. Applicant asserts that the unexpected results showing a synergeistic effect of the claimed compounds and chemotherapeutic agents are commensurate in scope with the amended claims.

Accordingly Applicant respectfully requests that this double patenting rejection be reconsidered and withdrawn.

2. Claims 1, 3-4, 6-13 and 23-25 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-38 of copending Application No. 10/547,077 in view of Ekwurlbe *et al* (U.S. 6,380,405).

As discussed in previous Amendment of October 9, 2009, Applicant respectfully points out that the October 2, 2003 filing date of the present application is earlier than the November 19, 2004 international filing date of the copending Application No. 10/547,077. Accordingly,

AMENDMENT UNDER 37 C.F.R. § 1.114(c)
U.S. Application No.: 10/530,176

Attorney Docket No.: Q86664

the Examiner should withdraw this double patenting rejection and permit this application to issue as a patent without a terminal disclaimer once all the other rejections are overcome. MPEP § 804(I)(B)(1).

VI. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

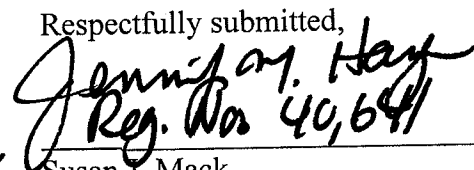
WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: November 12, 2009

Respectfully submitted,


for Susan J. Mack
Registration No. 30,951